

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

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UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 20-1744-CFC
	)	
WALMART INC. AND WAL-MART	)	
STORES EAST, LP,	)	
	)	
Defendant.	)	
	)	

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**OPENING BRIEF IN SUPPORT OF DEFENDANTS' PARTIAL MOTION  
TO DISMISS THE AMENDED COMPLAINT**

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## **NATURE AND STAGE OF PROCEEDINGS**

In this action, the Government seeks civil penalties and injunctive relief for alleged violations of the Controlled Substances Act (“CSA”). After Walmart moved to dismiss (D.I. 26), the case was stayed pending the Supreme Court’s decision in *Ruan v. United States*, 142 S. Ct. 2370 (2022). D.I. 59. The Government then opted to amend its pleading. D.I. 75 (“AC”). Walmart now moves to dismiss most of the AC for failure to state a claim.

## **SUMMARY OF ARGUMENT**

After a unanimous Supreme Court rebuked its overreaching CSA theories in *Ruan*, the Government was forced back to the drawing board. But the Amended Complaint continues to press a raft of novel theories that sweep too broadly and stretch the CSA and its regulations past the breaking point. More than 125 pages into the new pleading, the Government also alleges—for the first time after nearly six years of investigation—that particular Walmart pharmacists filled particular prescriptions those same pharmacists allegedly knew were invalid. Walmart does not seek to dismiss those prescription-by-prescription claims of knowing misconduct by trained professionals; Walmart will instead vigorously defend those claims on the facts. But the Court should reject on the law the rest of the Government’s case, which amounts to an effort to manufacture new legal duties, punishable by massive civil penalties, through retrospective litigation instead of prospective regulation.

**Count I.** CSA regulations forbid pharmacists to fill a particular prescription if they “know[]” it was issued outside “the usual course of professional treatment.” 21 C.F.R. § 1306.04(a). DEA added that strong scienter requirement to address pharmacists’ concerns about bearing “responsibility … to determine the legitimacy of a prescription.” 36 Fed. Reg. 7776, 7777 (Apr. 24, 1971). After all, pharmacists have neither the expertise nor the information to second-guess highly individualized medical judgments by state-licensed and DEA-registered doctors. As the Supreme Court observed in *Ruan*, the line separating medically valid and invalid prescriptions is “ambiguous” even for the prescriber, 142 S. Ct. at 2377; it is that much harder for a pharmacist standing outside the doctor-patient relationship to determine whether a particular prescription was written for a valid medical purpose.

The Government claims Walmart violated this rule, but its primary theory focuses on corporate compliance employees who never even saw the disputed prescriptions (or the patients who presented them), much less filled them. The Government says these employees knew certain doctors were suspected of lax prescribing, yet failed to adopt policies or systems to prevent pharmacists from *unknowingly* filling their prescriptions. That is Monday-morning quarterbacking about internal controls that the CSA and its regulations never required. Alleging that compliance employees could have set more aggressive corporate policies does not state a § 1306.04(a) claim for knowingly filling an invalid prescription.

Only after devoting hundreds of paragraphs to that legally flawed theory does the Government switch gears and identify particular prescriptions the *pharmacists* allegedly knew were invalid. That relatively small subset of prescription-by-prescription claims now contain sufficient (albeit inaccurate) factual particularity to survive dismissal. But they are interspersed with categorical, conclusory allegations that are legally inadequate. This Court should limit the Government's case to the specific prescriptions and violations as to which Walmart has been put on fair notice.

**Count II.** Another CSA regulation, 21 C.F.R. § 1306.06, limits dispensing to “the usual course” of professional pharmacy practice. The Government claims that Walmart pharmacists violated that rule by failing to investigate, resolve, and document “red flags” on prescriptions. But the Government misunderstands both the meaning of this rule and its place in the regulatory scheme. As the only two federal courts to have considered this issue recently agreed, this regulation does not trigger civil penalties or injunctive relief, but is subject only to *administrative* enforcement. Moreover, as Justice Alito explained in his *Ruan* concurrence, acting outside the usual course means no longer acting as a professional *at all*—something beyond even malpractice. The Amended Complaint alleges nothing of the sort. Its contrary approach—treating every departure from professional standards as itself a CSA violation—would swallow § 1306.04(a)'s scienter element, impose duplicative penalties, and transform minor state-law infractions into federal felonies.

**Count III.** Finally, the Government says that when Walmart self-distributed opioids to its own stores (which it did until 2018), its systems to detect and report “suspicious orders” were inadequate. Those allegations are unsupported, but in any event, the CSA at all relevant times provided only for administrative sanctions for such regulatory failures, not civil penalties. Moreover, the Government alleges that Walmart failed to report suspicious orders it *did not* discover, but the CSA even now does not impose civil penalties for *that*. For both reasons, Count III fails.

### **STATEMENT OF FACTS**

Walmart operates more than 5,000 pharmacies in communities nationwide. AC ¶ 3. Each pharmacy is registered with DEA. *Id.* ¶¶ 35, 53. Walmart pharmacists are authorized to dispense controlled substances pursuant to written prescriptions issued by state-licensed, DEA-registered doctors. *Id.* ¶¶ 7, 55.

In a Pharmacy Operations Manual that expanded in detail and depth over time, Walmart directed its pharmacists to fill only prescriptions they reasonably believed were valid and identified “red flags” for pharmacists to consider in evaluating validity. *Id.* ¶¶ 105, 119-22, 132-35. Following that guidance, Walmart pharmacists routinely refused to fill prescriptions they perceived as invalid based on the facts they knew. The Amended Complaint gives dozens of specific examples. *E.g., id.* ¶¶ 237, 246, 250, 257, 267, 280, 286, 304-05, 307, 316-18, 324-26, 342, 349-50, 357, 361, 371, 383-84, 421, 438, 440-42, 480-81, 503, 507, 526, 534.

As the Government itself recounts, Walmart consistently strove to improve its dispensing processes and protocols. For example, in 2015, Walmart introduced a platform that allowed pharmacists to search and review refusal-to-fill forms that other pharmacists had submitted. *Id.* ¶ 123. In 2017, Walmart authorized its pharmacists to refuse to fill for a prescriber on a “blanket” basis and instituted a procedure for corporate-level prescriber blocks as well. *Id.* ¶¶ 126-28.

Developing and implementing these policies fell within the bailiwick of the “compliance team” for Walmart’s Health and Wellness Division—a group of employees who sat in corporate headquarters in Arkansas. *Id.* ¶¶ 91-93. The compliance team received forms memorializing pharmacists’ decisions to refuse to fill prescriptions, and shared that refusal-to-fill data with DEA. *Id.* ¶¶ 98, 107-08. But these employees in Arkansas did *not* review particular prescriptions or decide whether to fill them. To the contrary, as the Government and the emails it quotes make clear, compliance managers routinely reiterated that it was pharmacists who had the duty and power “to exercise their professional judgment and choose to refuse to fill any prescription if they feel” it lacks a medical purpose. *Id.* ¶ 110; *infra* at 11.

The Amended Complaint also addresses Walmart’s role as a *distributor*. Until May 2018, Walmart self-distributed controlled substances to its pharmacies. *Id.* ¶¶ 82, 557. Over the relevant period, Walmart used several different systems to monitor for “suspicious orders” from its own stores. *Id.* ¶¶ 691-94, 700-08.

## ARGUMENT

### I. THE GOVERNMENT OVERREACHES IN CLAIMING THAT WALMART'S EMPLOYEES KNOWINGLY FILLED INVALID PRESCRIPTIONS.

Count I asserts that Walmart “knowingly fill[ed]” prescriptions “issued not in the usual course of professional treatment.” 21 C.F.R. § 1306.04(a). As a matter of basic agency principles, when the law forbids taking an action “knowingly” (or with another mental state), a corporation is liable only if a particular employee took that action with scienter. Yet the Government’s lead theory is *not* that the Walmart *pharmacists* who filled prescriptions knew they were invalid. Instead, it argues that Walmart’s *compliance employees* had the requisite “knowledge.” That is legally insufficient—and also factually implausible. The compliance team sat in company headquarters and developed corporate-level policies. These employees did not even see particular prescriptions, much less fill them, much less do so with scienter. This theory reduces to, at most, unfounded and unwarranted after-the-fact criticisms that Walmart’s corporate systems and internal policies were negligently designed. More importantly, these criticisms do not amount to § 1306.04(a) claims.

More than 400 paragraphs into its pleading, the Government alleges particular instances in which pharmacists at particular stores filled particular prescriptions they allegedly knew were outside the usual course. Walmart will vigorously defend those misleading claims on the facts. But the Government’s case must be limited to that subset of particularized claims on a prescription-by-prescription basis.

**A. The Government Cannot Establish Violations Using Knowledge from Compliance Employees Who Did Not Fill Prescriptions.**

When liability hinges on taking a particular action with knowledge of a certain fact, a corporation is liable only if a specific employee who takes that action for the company has the requisite knowledge. The Government cannot establish liability by combining one employee's knowledge with another employee's unknowing actions—here, the alleged knowledge of compliance employees in the company's headquarters about certain doctors' prescribing practices and the actions of pharmacists working in store pharmacies who actually filled particular prescriptions.

1. The applicable rule is black-letter agency law. “If knowledge ... is the important element in a transaction,” a principal is charged only with knowledge held by the employee “acting for the principal in the transaction.” *Restatement (Second) of Agency* § 275 cmt. b (1958). But if “the agent who has the knowledge is not one acting for the principal in the transaction,” that knowledge is *not* imputed; “the principal is not affected by the fact that the agent has the knowledge” and cannot be held “responsible” for it. *Id.*; *see also id.* § 268 cmt. d (where “state of mind is important,” knowledge that an employee “does not communicate” does not generally allow for liability for the principal).

For example, consider a law that “condition[s] a particular result on whether an individual person had personal knowledge of a fact,” as often is true for “criminal liability” or “imposition of penalties within certain licensing regimes.” *Restatement*

(*Third*) of Agency § 5.03 cmt. d(7) (2006). “In a corporate context, … the relevant personal knowledge is that of the individual who took the action that the statute criminalizes, or, in appropriate circumstances, the personal knowledge of the individual who directed or ratified the action taken.” *Id.*

Describing these principles, the Supreme Court recounted that “the malicious mental state of one agent cannot generally be combined with the harmful action of another agent to hold the principal liable.” *Staub v. Proctor Hosp.*, 562 U.S. 411, 418 (2011). And, indeed, that is the rule courts regularly apply.

This issue arises most often in securities fraud cases, where courts hold that corporate liability hinges on “the state of mind of the individual corporate official or officials who make or issue the statement” or otherwise participate in its creation, rather than “the collective knowledge of all the corporation’s officers and employees acquired in the course of their employment.” *Southland Sec. Corp. v. INSpire Ins. Sols., Inc.*, 365 F.3d 353, 366 (5th Cir. 2004); *see also id.* (citing “general common law rule” that governs when a claim requires “an essentially subjective state of mind” plus “some sort of conduct”); *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1118 (D.C. Cir. 2009) (“[W]e look to the state of mind of the individual corporate officers and employees who *made, ordered, or approved* the statement.” (emphasis added)); *Makor Issues & Rts., Ltd. v. Tellabs Inc.*, 513 F.3d 702, 707-08 (7th Cir. 2008) (same).

This Court, too, has refused to allow plaintiffs to state a securities fraud claim by “attributing false statements to one group” but “pleading scienter against another group.” *City of Roseville Emps.’ Ret. Sys. v. Horizon Lines, Inc.*, 713 F. Supp. 2d 378, 402-03 (D. Del. 2010), *aff’d*, 442 F. App’x 672 (3d Cir. 2011).

Courts apply the same principle in other contexts too. *E.g., United States v. Sci. Applications Int’l Corp.*, 626 F.3d 1257, 1275-76 (D.C. Cir. 2010) (employees’ knowledge cannot be combined with submission of false claim by other officials); *Woodmont, Inc. v. Daniels*, 274 F.2d 132, 137 (10th Cir. 1959) (representations by field employees cannot be combined with corporate directors’ knowledge of falsity); *Jehly v. Brown*, 327 P.3d 351, 354-55 (Colo. App. 2014) (similar).

In short, when liability requires action paired with a culpable mental state, a corporation can be liable only if those elements merge in a particular employee.

2. This principle forecloses the Government’s theory that Walmart is liable based on “knowledge of *any* corporate personnel.” AC ¶ 61 (emphasis added).

Section 1306.04(a) forbids “knowingly” dispensing an invalid prescription. Because knowledge is an “important element,” the inquiry must focus on the agent who acts for the pharmacy in the dispensing “transaction.” *Restatement (Second) of Agency* § 275 cmt. b. Indeed, this is the classic scenario in the Restatement, because § 1306.04(a) can trigger both “criminal liability” and “imposition of penalties” in a “licensing regime[.]” *Restatement (Third) of Agency* § 5.03 cmt. d(7).

Thus, the Government must allege that a particular employee *involved in dispensing a prescription* knew at that time that it was invalid. It is not enough to point to knowledge supposedly held by other employees who did not represent Walmart in that allegedly unlawful dispensing “transaction,” and who indeed did not even contemporaneously know of that transaction.

The Government’s primary theory, set out in § II.B.1 of the AC, does only the latter. It alleges that Walmart’s compliance employees were aware, from refusal-to-fill forms and other data, that certain prescribers were suspected of lax prescribing practices. AC ¶ 147. It also alleges these employees knew those doctors would keep writing prescriptions that patients would take to Walmart. *Id.* ¶ 148.

Even assuming those knowledge allegations are plausible, *but see infra* I.A.4 (explaining why they are not), they are legally insufficient. The Government cannot combine the *knowledge* of compliance employees with the *actions* of dispensing pharmacists. The compliance team worked out of corporate headquarters—not any pharmacy. AC ¶ 91. They worked on corporate-level “policies and procedures”—not decisions to fill (or refuse to fill) particular prescriptions. *Id.* ¶ 92. The Amended Complaint does not allege that compliance employees made or directed any of the dispensing decisions at issue. To the contrary, the Government admits that compliance employees routinely advised pharmacists to “exercise their professional judgment” in evaluating whether to fill or refuse to fill prescriptions. *Id.* ¶ 110.

Indeed, the emails the Government selectively quotes are perfectly clear that the compliance team could not and would not make or direct decisions on the validity of particular prescriptions. For example, it claims the compliance team was “uninterested in the details of government investigations of certain prescribers.” *Id.* ¶ 190. Actually, the cited email advised that “[o]nly Pharmacists are granted the ability to refuse to fill for professional reasons, not the permit holders (home office),” and urged pharmacists to use “their professional judgment when they get RX’s from prescribers with questionable prescribing habits.” Durfee Decl. Ex. A. In another email the Government selectively quotes (AC ¶ 166), the same manager explained it is “impossible for any of us here in the Home Office” to “determin[e]” the “validity of these prescriptions,” and the “decision to fill or not to fill rests with the individual pharmacists and cannot be mandated by the permit holders.” Durfee Decl. Ex. B.

The Amended Complaint contains one lone example of a compliance manager giving specific direction about a particular prescription—he “directed a pharmacist *not to fill*” one. AC ¶ 103 (emphasis added). And that directive arose only because hydrocodone had been rescheduled as a Schedule II controlled substance after the prescription was written; it had nothing to do with whether the prescription was medically legitimate or issued in the usual course. Durfee Decl. Ex. C.<sup>1</sup>

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<sup>1</sup> The Court may consider the full content of these emails at the pleading stage because the AC “explicitly relie[s]” on them. *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997).

In short, the compliance employees did not fill any prescriptions with scienter because they did not fill any prescriptions at all. Nor can their knowledge be mixed-and-matched with actions of Walmart pharmacists to cobble together a violation.

3. Rather than identify any prescriptions the compliance team filled or directed be filled, the Government claims their failures to act caused *others* to fill invalid prescriptions *unknowingly*. It objects that compliance employees took too long to integrate Walmart’s systems so pharmacists could access refusal-to-fill data. AC ¶¶ 195-208. It complains that those employees insisted pharmacists evaluate each prescription, as state regulators directed, rather than block doctors wholesale. *Id.* ¶¶ 110, 209-220. And it criticizes them for not prioritizing deeper data analytics. *Id.* ¶¶ 177-79. The Government says the result was that pharmacists, lacking full information, *unwittingly* filled invalid prescriptions. *See id.* ¶¶ 146-50. (Indeed, the Amended Complaint separately identifies situations where the pharmacists allegedly had knowledge, *infra* Part I.B; the “compliance” theory matters only if they did not.)

All this exposes that the Government’s § 1306.04(a) theory is really just a set of policy attacks on Walmart’s systems. Those objections fail to state a claim. Section 1306.04(a) imposes liability for *knowingly filling an invalid prescription*. It does not require information-sharing or corporate blocking or algorithmic analysis. And it certainly does not impose huge penalties on companies (or their individual employees, AC ¶ 60) who fail to adopt those policies quickly enough.

To be sure, Congress or the DEA could have imposed additional prophylactic duties on pharmacies to mitigate diversion—but never did so. Neither Congress nor the DEA ever made the policy judgment call that, for example, pharmacies should try to stem diversion by blocking all prescriptions from a licensed prescriber, even at the cost of blocking patients from access to needed medications. In any event, “an agency must have clearly communicated its policies before a private party may be sanctioned.” *United States v. Harra*, 985 F.3d 196, 213 (3d Cir. 2021). The Government cannot weaponize § 1306.04(a) to enforce non-existent duties or impose specific policy dictates after the fact, through the backdoor, by pretending that Walmart compliance employees “knowingly filled” invalid prescriptions when in reality they did not fill any prescriptions at all.

The Government’s creative approach to scienter “treats knowledge as a species of negligence, holding corporations liable not for their knowledge, but for failing to maintain open channels of communication.” Mihailis E. Diamantis, *Functional Corporate Knowledge*, 61 WM. & MARY L. REV. 319, 346-49 (2019). That “punishes corporations more than … Congress deemed just.” *Id.* at 349. And it thus fails to state a claim. *Accord Saba v. Compagnie Nationale Air France*, 78 F.3d 664, 670 n.6 (D.C. Cir. 1996) (refusing to use “acts of negligence on the part of employees” to “create a wrongful corporate intent”).

4. Although the points above are dispositive, the Government also fails to plausibly allege that the compliance team *knew* of any specific invalid prescription when it was filled (or even after). The compliance team did not interact with patients or prescribers and did not see particular prescriptions when presented at pharmacies. These employees had neither the information nor the responsibility to form a belief about the validity of any specific prescription, let alone the millions presented at thousands of pharmacies. It is thus not “plausible,” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), to allege they *knew* any particular prescription was invalid.

Nor does the Government allege a basis for willful blindness, which occurs when one “take[s] deliberate actions to avoid learning” of a fact despite subjectively believing “there is a high probability that [the] fact exists.” *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 769 (2011). Even assuming the compliance team believed there was a high risk of invalid prescriptions, the Amended Complaint does not allege they deliberately tried to “shield[] themselves,” *id.* at 766, from the facts, much less the facts about any specific prescription. It instead alleges only that the workgroup set up to analyze refusal-to-fill data did not “prioritize” it. AC ¶ 177-79. And it objects that, despite “recogniz[ing] the need” to adopt data-sharing systems, the team took too long to do so because it did not see the issue as “urgent.” *Id.* ¶ 198; *see also id.* ¶ 203 (manager’s email expressing desire to better “push the information to pharmacies”). That is far from a “deliberate” desire to remain blind.

To bridge this gap, the Government alleges that compliance employees knew certain doctors were operating as “pill-mills” and therefore knew that *every* future prescription those doctors wrote would be medically illegitimate under § 1306.04(a). But that inferential leap mistakes the relevant inquiry—which focuses on the *prescription*, not the *prescriber*. As DEA has long agreed, “each case must be evaluated based on its own merits in view of the totality of circumstances.” 71 Fed. Reg. 52716, 52720 (Sept. 6, 2006). Certain “red flags” may warrant case-by-case investigation, but they cannot establish that *all* of a doctor’s prescriptions are invalid.

The public record showcases the need for individual analysis. One prescriber apparently referenced in the AC was *acquitted* of all CSA violations; three more were acquitted as to *some* prescriptions.<sup>2</sup> Another had his prescribing upheld by a state medical board *after* Walmart supposedly knew all of his prescriptions were improper. AC ¶ 299; Durfee Decl. Ex. D.<sup>3</sup> And the Government does not allege that DEA has *even yet* stripped a sixth doctor of his right to prescribe controlled substances, even after suing Walmart for not blocking him *six years ago*. AC ¶ 242.

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<sup>2</sup> *United States v. Bird*, No. 8:18-cr-288, D.I. 128, 219 (M.D. Fla. May 21, 2021); *United States v. Kumar*, No. 4:17-cr-005, D.I. 86, 385 (E.D.N.C. Aug. 12, 2019); *United States v. Bynes*, No. 4:18-cr-153, D.I. 71, 152 (S.D. Ga. Oct. 10, 2019); *United States v. Titus*, No. 1:18-cr-045, D.I. 2, 101 (D. Del. July 21, 2021).

<sup>3</sup> This Court may take judicial notice of “public records,” including records from state administrative bodies, in resolving a motion to dismiss. *McCray v. Fid. Nat’l Title Ins. Co.*, 636 F. Supp. 2d 322, 325 n.4 (D. Del. 2009).

Identifying unlawful prescriptions is simply not the once-and-for-all task the Government now conjures. Its categorical approach to knowledge is legally flawed, and its compliance-team theory fails for this independent reason too.

**B. The Government Cannot Proceed on Vague Claims That Do Not Involve Particularized Allegations About Particular Prescriptions.**

On page 127 of the Amended Complaint, the Government switches gears and, for the first time, alleges in § II.B.2 that particular Walmart pharmacists filled certain prescriptions they knew were invalid. It identifies *particular* pharmacists that filled prescriptions for *particular* doctors or *particular* patients despite allegedly having knowledge that *those prescriptions* were invalid. *E.g.*, AC ¶¶ 455-57 (fills by Store 8134 for prescribers despite being “uncomfortable” with “all” of their prescriptions); *id.* ¶ 475 (fills by pharmacy manager in Missouri despite “admitted … knowledge that the prescriber was not adhering to the usual course”); *id.* ¶¶ 531-37 (fills by Store 3066 for patient M.I. despite “numerous obvious signs of invalidity”). Walmart maintains that the facts will show that these pharmacists applied their best efforts to satisfy an “ambiguous” rule, *Ruan*, 142 S. Ct. at 2377, in the face of imperfect information. But Walmart acknowledges that these allegations may be sufficiently particularized to satisfy the relatively generous Rule 12(b)(6) standard.

Still, the Government cannot use those limited, particularized claims to justify an unbounded, nationwide fishing expedition for unpled violations. It says each act of dispensing in violation of § 1306.04(a) triggers a separate civil penalty. AC ¶ 78.

Walmart is therefore entitled to fair notice of *each* particular allegedly unlawful act of dispensing. *See U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 719 F.3d 31, 39 (1st Cir. 2013) (affirming refusal to “expand the scope” of False Claims Act case based on “bald assertions” beyond false claims specifically alleged); *U.S. ex rel. Bledsoe v. Cmtv. Health Sys., Inc.*, 501 F.3d 493, 509, 524 (6th Cir. 2007) (affirming dismissal of certain paragraphs of complaint that did not allege “specific false claims”). Yet, interspersed within its particularized allegations, the Government adds a half-dozen broad, ill-defined, conclusory allegations that would expand the case by many orders of magnitude. AC ¶¶ 482, 489, 508, 513, 521-22.

For example, the Government identifies times that Walmart pharmacists dispensed trinity prescriptions or multiple immediate-release opioids when specific facts about the patient, doctor, or both allegedly made those prescriptions obviously invalid “on their face.” *See id.* ¶¶ 483, 488, 492, 495-96, 498, 501-03. Those allegations may state § 1306.04(a) claims for those identified prescriptions. But the Government also tries to generalize. It purports to challenge “thousands of prescriptions” because they fall into “four trinity categories” or were “for multiple immediate-release opioids on the same day or close in time,” with no particularized factual allegations about the circumstances of those prescriptions, even after years of investigation. *Id.* ¶¶ 482, 508. For two reasons, these catch-all paragraphs fail to state additional claims beyond the prescription-by-prescription allegations.

To start, their “factual detail … is so undeveloped that it does not provide” the requisite “notice.” *Phillips v. Cnty. of Allegheny*, 515 F.3d 224, 232 (3d Cir. 2008). For example, ¶ 482 purports to challenge “thousands” of prescriptions (nationwide, over five years) for multiple immediate-release opioids that were filled “close in time” and bore an unidentified “combination” of unspecified “other red flags.” It is impossible even to tell which prescriptions fall into that indeterminate category.

Moreover, these paragraphs lack particularized facts to support a “reasonable inference that the defendant is liable,” *Iqbal*, 556 U.S. at 678—i.e., facts showing that these prescriptions were actually invalid and the pharmacist knew as much. For example, even if trinities are “popular” for drug abuse (AC ¶ 492), that hardly means they are *per se* invalid or have no legitimate medical purposes. *See* 71 Fed. Reg. at 52720 (red flags do not “automatically” imply invalidity). The Government must plead and prove each § 1306.04(a) violation; it cannot rely on generalizations about entire categories of prescriptions that have concededly valid applications. *See Davis v. Abington Mem’l Hosp.*, 765 F.3d 236, 242-43 (3d Cir. 2014) (dismissing overtime claims where plaintiffs alleged what they did “typically” or “frequently” but did not identify a specific “single workweek” where work exceeded 40 hours); *Bennett v. Teva Pharms. USA Inc.*, Nos. 21-1642 & 21-2304, 2022 WL 4093739, at \*4 (3d Cir. Sept. 7, 2022) (dismissing “conclusory” claims that defendant “failed to report [to FDA] thousands of serious adverse medical events”).

For these reasons, the Court should dismiss the “compliance team” theory pleaded by § II.B.1 of the Amended Complaint, and should also dismiss any separate claims the Government means to assert in AC ¶¶ 482, 489, 508, 513, and 521-22.

## **II. THE GOVERNMENT DOES NOT STATE VIABLE CLAIMS UNDER § 1306.06.**

Count II invokes 21 C.F.R. § 1306.06, which provides that “[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.” According to the Government, a pharmacist violates that rule if she departs from “professional pharmacist practice standards.” AC at 15. And the Government claims (with no legal citation) that those standards require pharmacists to identify, resolve, and document resolution of any “red flags” before filling a prescription. *Id.* ¶¶ 70-75. It alleges that Walmart pharmacists sometimes skipped those steps because of “high volumes of customers,” “staffing shortages,” or similar pressures. *Id.* ¶ 549. It claims each such misstep generates a civil penalty, even if the prescription at issue was actually *valid*. *Id.* ¶¶ 76-77.

The Government is doubly mistaken. At the outset, there is no statutory basis to award civil penalties for violations of § 1306.06. The Government’s theory seems to be that *every* regulatory infraction triggers civil penalties under the CSA, but that is wrong—as both courts that have confronted this issue recently agreed. As relevant here, the CSA imposes civil penalties only for dispensing *without a prescription*, but that is simply not what the Government alleges in Count II.

Regardless, the Government is legally mistaken in treating any departure from professional practice standards as transgressing § 1306.06. As Justice Alito recently explained, “outside the usual course” refers to extreme misconduct, where the doctor or pharmacist can no longer be said to be acting as a professional *at all*. It does not expose doctors, pharmacists, and their employers to civil and criminal liability for ordinary deviations from best practices, which is all that is alleged here.

The Government’s contrary approach would make nonsense of the regulatory scheme: It would render superfluous § 1306.04(a)’s targeted approach to scienter and subject every professional error to severe and duplicative federal penalties.

#### **A. Violations of § 1306.06 Do Not Give Rise to Civil Penalties.**

To start, Count II fails because § 1306.06 is not punishable by civil penalties, the relief the Government seeks here. Rather, like many regulations, § 1306.06 can only be enforced administratively, *e.g.*, by revocation of a pharmacy’s registration.

The CSA authorizes the Attorney General to promulgate rules “relating to … dispensing of controlled substances.” 21 U.S.C. § 821. But it does not impose civil penalties for every violation of a regulation. Rather, it enumerates a closed list of violations that trigger penalties. *Id.* § 842(a), (c)(1). Other rules are enforced administratively; DEA is empowered to revoke registrations using an open-ended “public interest” test that accounts for compliance with all laws. *Id.* §§ 823(f), 824(a). Revocation is a serious sanction, and its threat carries deterrent effects.

The Government here, however, seeks civil penalties, relying on 21 U.S.C. § 842(c)(1)(A). That section imposes penalties for violations of § 842(a)(1), which makes it unlawful to “dispense a controlled substance in violation of section 829.” Through a tortured series of cross-references, the Government claims that all of “Part 1306 of 21 C.F.R.”—*i.e.*, all the regulations governing prescriptions for controlled substances—are incorporated into § 829’s “limited dispensing authorization.” AC ¶¶ 56, 62-67. The Government’s theory is therefore that *any* regulatory infraction relating to prescriptions somehow violates § 829 and triggers civil penalties.

That is wrong. On its face, § 829 is limited to prohibiting dispensing controlled substances “without the written prescription of a practitioner.” 21 U.S.C. § 829(a). Thus, only dispensing *without a prescription* triggers a civil penalty for violating that provision. Unless a pharmacist dispenses “without” a “prescription,” she has not violated § 829 and there is no basis for imposing a civil penalty.

A bare violation of § 1306.06 does not itself entail a violation of 21 U.S.C. § 829 and therefore does not give rise to civil penalties. Section 1306.06 explains *who* may fill prescriptions: “only … a pharmacist.” 21 C.F.R. § 1306.06. It then explains *how* pharmacists may fill those prescriptions: “in the usual course of … professional practice.” *Id.* But a pharmacist who violates that regulation does not also violate § 829, unless she has dispensed *without a prescription*. The regulatory violation alone therefore does not trigger a civil penalty under the CSA.

For example, consider a pharmacist who resolves a “red flag” before filling a valid prescription but does not document that resolution. On the Government’s view, if the pharmacist neglects to record that resolution in her file, she has violated § 1306.06. Yet she has obviously not dispensed “without the written prescription of a practitioner” in violation of § 829. As this example shows, a violation of § 1306.06 does not imply a violation of § 829, and so provides no pathway to civil penalties.

Section 1306.04(a) is a telling contrast. It defines what *is* a valid prescription: “A prescription ... to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 C.F.R. § 1306.04(a). And it defines what is *not* one: “An order purporting to be a prescription issued not in the usual course of professional treatment ... is *not* a prescription within the meaning and intent of [21 U.S.C. § 829].” *Id.* (emphasis added). The regulation then spells out the consequence of those definitions: “[T]he person knowingly filling such a purported prescription ... shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” *Id.* That consequence makes sense: Those who knowingly fill such a prescription have dispensed “without” a “written prescription” in violation of 21 U.S.C. § 829, because the prescription did not satisfy the agency’s interpretation of what defines a valid “prescription.” That is why § 1306.04(a)—unlike § 1306.06—expressly references § 829 and the imposition of “penalties” under the CSA.

This interpretation coheres with the regulatory framework. Civil penalties kick in when doctors write (and pharmacists knowingly fill) invalid prescriptions, which strike at the CSA’s core. Those penalties are not, however, a tool to enforce “best practices.” Rather, if DEA is concerned about a pharmacy’s deviation from professional standards, the proper course is to revoke its registration or threaten to do so (and to report negligent pharmacists to state regulators for discipline).

The Government has advanced its novel § 1306.06 theory in two other courts. Both correctly rejected it and dismissed the claims. *United States v. Ridley’s Fam. Mkts., Inc.*, No. 20-cv-173, 2021 WL 2322478, at \*4 (D. Utah June 7, 2021); *United States v. Howen*, No. 21-cv-106, D.I. 27, at 16-18 (E.D. Cal. Aug. 9, 2022). This Court should do the same.

In short: If a pharmacist knowingly fills an invalid prescription, that violates § 1306.04(a) and 21 U.S.C. § 829, triggering a penalty for dispensing without a valid prescription. But there is no *second* penalty if, in filling an invalid prescription, the pharmacist failed to identify, resolve, or document a red flag. And if the prescription was valid or the pharmacist lacked knowledge of its invalidity, there is *no* violation of § 829 and *no* penalty—even if the pharmacist violates § 1306.06 in her treatment of a red flag.<sup>4</sup> For that reason alone, the Court should dismiss Count II.

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<sup>4</sup> Nor is there a basis for injunctive relief. 21 U.S.C. § 843(f) authorizes “injunctive relief relating to violations of … section 842,” but as explained, a regulatory violation of § 1306.06 does not amount to a statutory violation of § 842.

**B. Section 1306.06 Does Not Prohibit Every Deviation from Best Standards of Professional Conduct.**

Count II must also be dismissed for an independent reason: The Government is wrong about the substantive meaning of § 1306.06 and has not adequately alleged any violation under a proper construction. Again, that rule provides that pharmacists may dispense controlled substances only when they are acting *in their capacity as pharmacists*. That does not codify every professional aspiration into federal law.

The Government maintains that every time a pharmacist fails to meet her “professional responsibilities”—allegedly including duties to “identify,” “resolve,” and “document” red flags—the pharmacist has acted outside the usual course of her professional practice in violation of § 1306.06. AC ¶¶ 71-74. That is wrong.

In *Ruan*, Justice Alito (joined by Justices Thomas and Barrett) explained that acting “in the course of … professional practice” does not mean “conform[ing] to the standards of medical practice,” as that would conflate “acting ‘as a physician’” with “acting as a good physician.” 142 S. Ct. at 2388-89 (Alito, J., concurring in the judgment). “A doctor who makes negligent or even reckless mistakes in prescribing drugs is still ‘acting as a doctor’—he or she is simply acting as a bad doctor.” *Id.* at 2389. A doctor only departs from the course of professional practice by pursuing objectives “alien to medical practice,” such as “purposefully” facilitating “abuse.” *Id.* This part of the concurrence was not disputed by the majority, which construed § 841(a)’s scienter language in a way that did not require addressing the issue.

Justice Alito’s account honors established precedent. Courts have long held that merely falling short of best professional standards—and even committing “medical malpractice,” *United States v. Rottschaefer*, 178 F. App’x 145, 146 (3d Cir. 2006)—does not take a doctor outside the realm of usual practice. Rather, a doctor leaves the usual course of practice only when he acts “as a large-scale ‘pusher’—not as a physician,” *United States v. Moore*, 423 U.S. 122, 143 (1975), or otherwise “ceases to be a physician *at all*,” *United States v. Feingold*, 454 F.3d 1001, 1010-11 (9th Cir. 2006); *see also United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994) (outside usual course means assisting “in the maintenance of a drug habit” or dispensing for “personal profit”); *United States v. Volkman*, 797 F.3d 377, 388 (6th Cir. 2015) (proof of “negligen[ce]” insufficient); *United States v. McIver*, 470 F.3d 550, 560 (4th Cir. 2006) (“Malpractice or negligence” differs from acting “outside the bounds of … professional medical practice.”).

A pharmacist therefore does not abandon the “usual course” simply by failing to abide by professional best practices. She violates this provision only if she effectively stops acting as a pharmacist “*at all*” and instead acts as a drug “pusher” operating for “personal profit” or other “alien” objectives—*e.g.*, selling opioids for cash out of a pharmacy’s parking lot. The “usual course” question asks whether the professional is acting as a professional “*at all*,” not whether she is a “*bad*” one. *Feingold*, 454 F.3d at 1007, 1011. That is a much higher standard.

Judged against that proper standard, the Amended Complaint fails to state a claim that any of Walmart’s pharmacists filled a prescription while failing to “ac[t] in the usual course of professional practice.” It alleges nothing close to suggesting that Walmart or any of its pharmacists were ever “pushing” drugs or acting for “personal profit” rather than in a professional capacity. To the contrary, it makes clear that Walmart’s pharmacists took their professional duties seriously, struggled with the decisions they faced, and raised concerns when they had them. *See* AC ¶¶ 144, 155, 222-23. Even if the Government were correct that Walmart pharmacists occasionally deviated from alleged norms because they were too busy to investigate every red flag or document every resolution of one (AC ¶ 549), those departures would not rise to violations § 1306.06. This fundamental flaw in the Government’s reading of the regulation independently requires dismissal of Count II.

### **C. The Government’s Contrary Construction Is Untenable.**

The Government’s contrary approach to this regulation—reading it to forbid any deviation from professional norms, under pain of the CSA’s civil penalties—would confound the regulatory scheme and generate absurd results.

*First*, the Government’s reading of § 1306.06 would render § 1306.04(a) “inoperative, superfluous, and meaningless.” *Howen, supra*, D.I. 27, at 18; *see also Ridley’s*, 2021 WL 2322478, at \*4. As discussed above, § 1306.04(a) imposes liability on pharmacists who “knowingly fill[]” a “prescription issued not in the usual

course of professional treatment.” But there is no scenario in which a pharmacist *knowingly* fills an invalid prescription *without* departing from “basic professional obligations of pharmacists.” AC ¶ 547. Section 1306.04(a) would thus have no role left to play under the Government’s reading of § 1306.06. Yet it is “a basic tenet of statutory construction, equally applicable to regulatory construction,” that a scheme “should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, … and so that one section will not destroy another.” *Silverman v. Eastrich Multiple Inv. Fund, L.P.*, 51 F.3d 28, 31 (3d Cir. 1995). The Government violates that principle.

*Second*, and making matters worse, the DEA added the “knowingly” scienter requirement to § 1306.04(a) specifically to protect pharmacists, who do not practice medicine and do not have access to the information doctors use for diagnosis and treatment. *See* 36 Fed. Reg. at 7777. Yet on the Government’s interpretation of § 1306.06, a pharmacist is liable for every procedural misstep in dispensing a prescription, even if she sincerely believes the prescription was issued in the usual course for legitimate medical purposes, and even if the prescription *actually was* issued in the usual course for legitimate medical purposes. AC ¶ 75. That “would render § 1306.04(a) and its knowledge requirement meaningless,” because it would allow the Government to “successfully bring a claim against a pharmacist under § 1306.06 for filling prescriptions … even if there was not enough evidence to show

the pharmacist had knowledge of their illegitimacy.” *Ridley’s*, 2021 WL 2322478, at \*4. Indeed, if a pharmacist in good faith filled a red-flag prescription that turned out to be invalid, the Government could just invoke the more expansive § 1306.06 and argue that the pharmacist should have done more to identify the invalidity. It is hard to think of a clearer example of one rule being read in such an overbroad way that it “destroy[s]” another. *Silverman*, 51 F.3d at 31.

*Third*, reading § 1306.06 to forbid every deviation from professional norms, on pain of civil penalties, would lead to absurd results. Like other professionals, pharmacists must follow a long list of state-law regulations. *E.g.*, 24 Del. Admin. Code § 2500-5.2.1 (pharmacists must provide counseling that “may include,” *e.g.*, “action to be taken in the event of a missed dose”). State law often imposes only administrative sanctions, not criminal or civil penalties, for violating these rules. *E.g.*, Del. Code Ann. tit. 24, § 2516 (authorizing letters of reprimand, suspension or revocation of license, and “administrative penalt[ies]” of up to \$500). But on the Government’s view, federal law supplements that state-law scheme with additional penalties—including *tens of thousands of dollars in fines*—every time a pharmacist departs from those same rules. That violates the Supreme Court’s warning against interpreting federal law in a way that “involves the Federal Government in setting standards” reserved for state law. *McNally v. United States*, 483 U.S. 350, 360 (1987). And that canon is particularly appropriate for the CSA, which was never

meant to “effect a radical shift of authority from the States to the Federal Government to define general standards of medic[ine].” *Gonzales v. Oregon*, 546 U.S. 243, 275 (2006).

Finally, the Government’s reading would subject a pharmacist to *criminal* liability for any deviation from professional standards of practice that is undertaken “knowingly,” 21 U.S.C. § 842(c)(2)(A). That means a pharmacist who knowingly neglects to fill out some paperwork required by a state pharmacy board, for example, can be sent to federal prison. Once again, canons of construction prohibit this interpretation. The rule of lenity demands that any ambiguity in laws like this one—with both civil and criminal applications—be resolved in the defendant’s favor. *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004). And courts should not lightly read a federal criminal statute to intrude upon an area of “traditional state concern,” *Jones v. United States*, 529 U.S. 848, 858 (2000), or assume Congress delegated the power to make federal criminal laws to 50 different state regulatory boards.

All told, the Government’s interpretation of § 1306.06 would “nullify the knowledge requirement in § 1306.04(a),” contradict the latter’s “clearly expressed administrative intent,” “severely interfere with pharmacists’ essential jobs,” and “ultimately damage patients who need these controlled substances for legitimate medical purposes.” *Ridley’s*, 2021 WL 2322478, at \*4. This Court should dismiss Count II.

### **III. THE GOVERNMENT CANNOT RECOVER CIVIL PENALTIES FOR ALLEGED HISTORICAL FAILURES TO DETECT AND REPORT SUSPICIOUS ORDERS.**

Finally, Count III concerns Walmart’s *distribution* of opioids to its own stores.

Walmart ceased self-distribution in May 2018, so the Government seeks only retrospective civil penalties (not prospective injunctive relief) based on that conduct. AC ¶¶ 82, 770-72. The Government alleges that Walmart violated a rule requiring distributors to “design and operate a system to disclose … suspicious orders” and to “inform” DEA of those orders “when discovered.” 21 C.F.R. § 1301.74(b). The Court should dismiss this count for two independent legal reasons.

*First*, the CSA did not, at the relevant time, impose civil monetary penalties for violations of this duty. The AC cites a statute penalizing failures to make reports “required under this subchapter,” 21 U.S.C. § 842(a)(5), but Walmart’s reporting obligation was at the time only *regulatory* and therefore did not trigger that penalty. Congress confirmed as much by later amending the CSA to add a statutory duty to report suspicious orders and to specify an accompanying civil penalty.

*Second*, the regulatory reporting duty covers only suspicious orders that the distributor *discovers*. Here, the Government primarily alleges that, because of its allegedly inadequate monitoring, Walmart failed to detect—in other words, *did not discover*—many suspicious orders. Yet on no reading of the statute is a distributor liable for civil penalties for failing to identify suspicious orders in the first place.

**A. Before October 2018, the CSA Did Not Authorize Civil Monetary Penalties for Failing To Report Suspicious Orders.**

As its basis for civil penalties under Count III, the Government invokes a CSA provision that prohibits failing “to make, keep, or furnish” any “record, report,” and so forth “required *under this subchapter*.” 21 U.S.C. § 842(a)(5) (emphasis added). Violations are subject to civil penalties. *Id.* § 842(c)(1)(B) (2012). The CSA does require registrants to make, keep, or furnish various records. *E.g.*, *id.* § 827(a)(1), (3); *id.* § 828(c). Yet, until amended in late 2018, it did *not* require distributors to “make, keep, or furnish” reports of suspicious orders. *See* 21 U.S.C. § 842 (2018). As the Amended Complaint admits (¶¶ 558-59), only a *regulation* did: 21 C.F.R. § 1301.74(b). Those suspicious-order reports were therefore not “required under this subchapter” within the meaning of § 842(a)(5), because they were not mandated by the CSA itself. DEA could have revoked a distributor’s registration for failure to comply with the regulatory reporting rule—but civil penalties were not available.

The Supreme Court’s decision in *Kucana v. Holder*, 558 U.S. 233 (2010), confirms that reports required “under this subchapter” exclude those required only by regulation. There, Congress stripped courts of jurisdiction to review certain immigration decisions “specified *under this subchapter* to be in the discretion of the Attorney General.” 8 U.S.C. § 1252(a)(2)(B)(ii) (emphasis added). The lower court held that it lacked jurisdiction over a decision because a *regulation* conferred discretion on the Attorney General to make it. 558 U.S. at 240-41.

The Supreme Court disagreed. (Indeed, even the Government disagreed. *Id.* at 242.) The Court held that the “key words ‘specified under this subchapter’” referred “to statutory, but not to regulatory, specifications.” *Id.* at 237. It gave three reasons. *First*, “statutory context” so suggested, because surrounding subsections also referred to *statutory* grants of discretion—while in other provisions, Congress had expressly referred to the Act “or regulations issued thereunder.” *Id.* at 245-48. *Second*, the “history of the relevant statutory provisions” corroborated that reading, including because Congress later amended the Act and “did not disturb” lower-court decisions limiting the jurisdiction-stripping provision. *Id.* at 249-51. *Third*, any “lingering doubt” was “dispelled” by a “familiar” canon of construction: the “presumption favoring judicial review of administrative action.” *Id.* at 251.

Each of those considerations applies equally (if not more strongly) here. *First*, the surrounding subsections of § 842(a) generally refer to *statutory* violations. *E.g.*, 21 U.S.C. § 842(a)(1) (dispensing “in violation of section 829”); *id.* § 842(a)(3) (distribution “in violation of section 825”); *id.* § 842(a)(4) (removal of label required “by section 825”); *id.* § 842(a)(7) (removal of seal placed “pursuant to section 824(f) or 881”); *id.* § 842(a)(10) (negligent failure to keep record “under section 830”). Given its “statutory placement, sandwiched between” these references to statutory duties, “one would expect that” § 842(a)(5), “too, would cover statutory [duties] alone.” *Kucana*, 558 U.S. at 246.

Moreover, “[i]n other provisions” of the Act, Congress “expressed precisely” its desire to sweep in regulatory duties. *Id.* at 248. One later subsection of § 842(a) does so, forbidding disclosure “in violation of regulations under subparagraph (C) of section 830(e)(1) of this title.” 21 U.S.C. § 842(a)(14). Elsewhere in the CSA, Congress repeatedly referred expressly to the statute *and regulations*. *See, e.g., id.* § 828(a) (“in accordance with subsection (d) *and regulations*”); *id.* § 829(f)(1) (“in accordance with this subchapter, *regulations prescribed by the Attorney General, and State law*”); *id.* § 880(d)(1) (“enforcement of this subchapter *or regulations thereunder*”) (all emphases added). As in *Kucana*, these contrasts underscore that § 842(a)(5) imposes liability only for reports required by the CSA itself. *Russello v. United States*, 464 U.S. 16, 23 (1983) (“We refrain from concluding ... that the differing language in the two subsections has the same meaning in each.”).

*Second*, the “history of the relevant statutory provisions” is even more powerfully corroborative than in *Kucana*, 558 U.S. at 249. There, the Court relied on an amendment that merely “did not disturb” the key language after lower-court rulings. *Id.* at 251. That is fairly weak evidence of statutory meaning. *See Bostock v. Clayton Cnty.*, 140 S. Ct. 1731, 1747 (2020). Here Congress specifically amended the CSA (after the time-frame relevant to this case) to require suspicious-order reporting—an amendment that would have had no purpose or effect if statutory and regulatory reporting duties already carried identical force and penalties.

Not until October 2018—after Walmart ceased being a distributor—did Congress amend the CSA to require suspicious-order reporting. Pub. L. No. 115-271, 132 Stat. 3894 (2018); 21 U.S.C. § 832(a). Congress also specified civil penalties for recordkeeping violations “related to the reporting of suspicious orders for opioids.” 21 U.S.C. § 842(c)(1)(B)(ii). “When Congress acts to amend a statute, [courts] presume it intends its amendment to have real and substantial effect.” *Intel Corp. Inv. Pol’y Comm. v. Sulyma*, 140 S. Ct. 768, 779 (2020). Congress’ decision to amend the CSA to require suspicious-order reports (and to specify penalties for failing to file them) is further proof that civil penalties were unavailable beforehand. Otherwise, the congressional amendment would have accomplished nothing.

*Finally*, any “lingering doubt” is “dispelled” by a “familiar principle of statutory construction.” *Kucana*, 558 U.S. at 251. Once again, the relevant canon is the rule of lenity, which requires narrow construction of ambiguous provisions carrying criminal penalties. *Cleveland v. United States*, 531 U.S. 12, 25 (2000). As explained, *supra* Part II.C, § 842 has “both criminal and noncriminal applications,” so the rule of lenity “applies” in construing it. *Leocal*, 543 U.S. at 11 n.8; *see* 21 U.S.C. § 842(c)(2)(A) (criminal penalties); *see also* *Burrage v. United States*, 571 U.S. 204, 216-17 (2014) (applying lenity to CSA). That means the narrower reading of this provision—excluding regulatory reporting obligations—must prevail if the statute is otherwise ambiguous. And this provision is *at minimum* ambiguous.

For these reasons, the Government cannot obtain penalties (the only relief it seeks) based on Walmart’s alleged failure to file suspicious-order reports that were required only by regulation. The Court should dismiss Count III.

**B. In Any Case, the CSA Did Not Authorize Monetary Penalties for Suspicious Orders That Escaped Detection.**

Even if civil penalties were otherwise available for reporting failures under 21 C.F.R. § 1301.74, that regulation requires reporting only when suspicious orders are “discovered by the registrant” through a monitoring system. 21 C.F.R. § 1301.74(b). That is, the rule’s first sentence directs registrants to “design and operate a system to disclose to the registrant suspicious orders.” *Id.* The second sentence then directs registrants to “inform” the DEA “of suspicious orders when discovered.” *Id.* The second sentence’s *reporting* duty is therefore triggered only when an order is flagged pursuant to the first sentence’s *monitoring* duty. Indeed, if the reporting duty applied to *all* suspicious orders (whether flagged or not), there would have been no need to spell out a separate duty to design a monitoring system.

In other words, the regulation does not expect registrants to report suspicious orders they did not detect. That makes perfect sense. The DEA has never fully defined “suspicious order,” and it would be severely inequitable to impose penalties based on DEA’s after-the-fact determination that a particular undetected order should have been reported. Rather, penalties kick in only when a distributor flags a suspicious order—and then fails to report it.

For those reasons, the Government grounds its demand for civil penalties in the claim that Walmart “did not report” suspicious orders. AC ¶ 559. But its factual allegations do not match its legal theory. The primary thrust of the allegations is that there were “defects” in “Walmart’s SOM program” (*id.* ¶¶ 576, 580-81), and Walmart therefore *failed to detect* the allegedly suspicious orders in the first place. *See also id.* ¶ 596 (“SOM system was deficient”), ¶ 598 (system allegedly “failed to flag” suspicious orders), ¶¶ 599-630 (identifying “flaws in Walmart’s approach to monitoring”); *id.* at 167, 169 (alleging that Walmart “failed to detect” suspicious orders). The Government’s principal theory is thus that Walmart’s systems suffered from defects “leading to underreporting” (*id.* ¶ 577)—not that Walmart failed to report suspicious orders “when discovered,” 21 C.F.R. § 1301.74(b).

Even the Government does not claim, however, that it can obtain penalties for *detection* failures. The statute authorizes civil penalties only for recordkeeping and reporting violations—not for inadequate monitoring systems. 21 U.S.C. § 842(a)(5). Of course, there is a remedy for an inadequate monitoring system: The DEA can revoke a distributor’s registration. *Id.* § 824(a)(4). But DEA never sought to revoke Walmart’s registration. And Walmart no longer distributes any controlled substances. For this reason too, the Court should dismiss Count III.<sup>5</sup>

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<sup>5</sup> Although clearly not its thrust, the Amended Complaint does include some allegations that Walmart failed to report suspicious orders it had identified. Those allegations fail for the reasons explained in Part III.A.

## CONCLUSION

For these reasons, the Court should dismiss the Amended Complaint in part.

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**WORD COUNT CERTIFICATION**

The undersigned hereby certifies that Defendants' Opening Brief in Support of its Motion to Dismiss contains 8,900 words (exclusive of the cover page, table of contents, table of authorities, and signature block) in Times New Roman 14-point font, counted using Microsoft Word's word count feature.

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